

इंटरनेट

मानक

Disclosure to Promote the Right To Information

Whereas the Parliament of India has set out to provide a practical regime of right to information for citizens to secure access to information under the control of public authorities, in order to promote transparency and accountability in the working of every public authority, and whereas the attached publication of the Bureau of Indian Standards is of particular interest to the public, particularly disadvantaged communities and those engaged in the pursuit of education and knowledge, the attached public safety standard is made available to promote the timely dissemination of this information in an accurate manner to the public.

“जानने का अधिकार, जीने का अधिकार”

Mazdoor Kisan Shakti Sangathan

“The Right to Information, The Right to Live”

“पुराने को छोड़ नये के तरफ”

Jawaharlal Nehru

“Step Out From the Old to the New”

IS 3829-3 (1985): Steam Sterilizers, Part 3: Pressure Sterilizers, Vertical Cylindrical Type [MHD 12: Hospital Equipment]



“ज्ञान से एक नये भारत का निर्माण”

Satyanarayan Gangaram Pitroda

“Invent a New India Using Knowledge”



“ज्ञान एक ऐसा खजाना है जो कभी चुराया नहीं जा सकता है”

Bhartrhari—Nitiśatakam

“Knowledge is such a treasure which cannot be stolen”

BLANK PAGE



IS : 3829 (Part 3) - 1985
(Reaffirmed 1996)

Indian Standard
**SPECIFICATION FOR
STEAM STERILIZERS**

**PART 3 PRESSURE STERILIZERS, VERTICAL
CYLINDRICAL TYPE**

(First Reprint APRIL 1998)

UDC 615.478.73 : 614.486.4 [621-98]

© Copyright 1985

**BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002**

Indian Standard

SPECIFICATION FOR STEAM STERILIZERS

PART 3 PRESSURE STERILIZERS, VERTICAL CYLINDRICAL TYPE

Hospital Equipment Sectional Committee, CPDC 14

Chairman

DR L. R. PATHAK
Dr B. L. Kapur Memorial Hospital
Pusa Road, New Delhi

Members

DR R. K. AGARWAL
DR R. N. GUPTA (*Alternate*)
BRIG N. K. BISWAS
SHRI K. M. DARGAR

SHRI A. R. DEY
SHRI H. C. SHAHI (*Alternate*)
SHRI M. DHARMAPANDIAN

JOINT DIRECTOR OF INDUSTRIES

ASSISTANT DIRECTOR OF
INDUSTRIES (*Alternate*)

DR (SMT) LALITHA KAMESWARAN

SHRI K. MANIVANNAN

SHRI P. K. NARULA

LT-COL B. PARGHI

SHRI V. K. BAPPAI (*Alternate*)

SHRI T. R. U. PILLAI

SHRI DARAYUS BHATHANA (*Alternate*)

SHRI R. B. SETHI

SHRI D. A. SHAH

SHRI P. M. PATEL (*Alternate*)

Representing

Ministry of Railways

Ministry of Defence (DGAFMS)
Office of the Development Commissioner
(Ministry of Industry), New Delhi
Ministry of Defence (R & D), Kanpur

Directorate of Industries & Commerce, Govern-
ment of Tamil Nadu, Madras
Directorate of Industries, Government of
Maharashtra, Bombay

Health and Family Welfare Department, Govern-
ment of Tamil Nadu, Madras

Directorate of Industries, Government of
Haryana, Chandigarh

All India Instrument Manufacturing and Dealers
Association, Bombay

Ministry of Defence (DGI)

Nat Steel Equipment Pvt Ltd, Bombay

International Industries, Bombay

Precision Electronics & Components, Bombay

(*Continued on page 2*)

© Copyright 1985

BUREAU OF INDIAN STANDARDS

This publication is protected under the *Indian Copyright Act* (XIV of 1957) and reproduction in whole or in part by any means except with written permission of the publisher shall be deemed to be an infringement of copyright under the said Act.

IS : 3829 (Part 3) - 1985

(Continued from page 1)

<i>Members</i>	<i>Representing</i>
SRI SUDHIR V. SHAH	MSCO Private Limited, Bombay
SRI C. V. NAWANI (<i>Alternate I</i>)	
SRI SHRIKANT SHAH (<i>Alternate II</i>)	
SRI J. C. SHANDILYA	Tempo Instruments & Equipments Pvt Ltd, Bombay
SRI J. R. PRABHU (<i>Alternate</i>)	
DR N. A. SIDDIQUI	Prince Aly Khan Hospital, Bombay
SRI D. M. TALWAR	Government Institute of Surgical Instruments Technology, Sonapat
SRI K. K. TANEJA	Directorate General of Technical Development, New Delhi
SRI KULWANT SINGH (<i>Alternate</i>)	
SRI BABULAL TODI	Todi Industries Private Ltd, Bombay
DR H. P. VARMA	In personal capacity
SRI R. J. A. VASAN	Surgiments (India), Bangalore
SRI BHASKARAN (<i>Alternate</i>)	
SRI R. N. VIG	Ultradent Pvt Ltd, Bombay
SRI D. N. VIG (<i>Alternate</i>)	
DR A. S. SETHI, Director (Consr Prods & Med Instrs)	Director General, ISI (<i>Ex-officio Member</i>)

Secretary

SRI D. K. AGRAWAL
Joint Director (Consr Prods & Med Instrs), ISI

Sterilizers, Autoclaves, Dressing Drums and Accessories Subcommittee, CPDC 14 : 3

Convener

SRI T. R. U. PILLAI Nat Steel Equipment Pvt Ltd, Bombay

Members

SRI DARAYUS BHATHENA (<i>Alternate to</i> Sri T. R. U. Pillai)	
SRI V. K. BAJPAI	Ministry of Defence (DGI)
SRI J. N. VISHWAKARMA (<i>Alternate</i>)	
COL S. K. DATTA	Ministry of Defence (DGAMFS)
MAJ B. SADANANDA (<i>Alternate</i>)	
SRI R. B. SETH	International Industries, Bombay
SRI D. A. SHAH	Precision Electronics Instruments and Components, Bombay
SRI P. M. PATEL (<i>Alternate</i>)	
SRI KIRIT M. SHAH	Medicare Equipment Co, Vadodara
SRI S. SREEDHAR (<i>Alternate I</i>)	
DR SHIRISH SHAH (<i>Alternate II</i>)	
SRI SUDHIR SHAH	MSCO Private Limited, Bombay
SRI C. V. NAWANI (<i>Alternate I</i>)	
SRI SHRIKANT V. SHAH (<i>Alternate II</i>)	
DR R. C. SHARMA	Directorate General of Health Services, New Delhi
DR G. K. BISWAS (<i>Alternate</i>)	
DR H. P. VARMA	In personal capacity
SRI R. N. VIG	Ultradent Pvt Ltd, Bombay
SRI D. N. VIG (<i>Alternate</i>)	

Indian Standard

SPECIFICATION FOR STEAM STERILIZERS

PART 3 PRESSURE STERILIZERS, VERTICAL CYLINDRICAL TYPE

0. F O R E W O R D

0.1 This Indian Standard was adopted by the Indian Standards Institution on 22 May 1985, after the draft finalized by the Hospital Equipment Sectional Committee had been approved by the Consumer Products and Medical Instruments Division Council.

0.2 Adequate provisions have been made throughout the standard for the safety and satisfactory design of the apparatus, bearing in mind the fact that a good deal of latitude is to be allowed to the individual manufacturer of sterilizers to introduce innovations and refinements.

0.3 The problem of explosion risk arising from fumes of anaesthetic agents have not been taken into consideration on the understanding that sterilizers dealt with in this standard would be installed generally remote from the anaesthetizing area in the operation theatre, and that the anaesthetic room would be outside the zone of explosion risk. Installation of these sterilizers is not recommended in an operation theatre.

0.4 This standard covers, by and large, the performance aspects of sterilizers. Dimensions of component parts have not been specified. It is recognized that some parts of the sterilizers may have to be replaced during use. For this reason, it is essential that the manufacturers should so design their sterilizers that the spare parts of any particular size are interchangeable within one's manufacture.

0.5 In the preparation of the standard considerable assistance has been derived from the following publications:

BS 3970 : Part 1 : 1966 Steam sterilizers, Part 1 Sterilizers for porous loads. British Standards Institution.

BS 3970 : Part 2 : Steam Sterilizers, Part 2 Sterilizers for bottled fluids, British Standards Institution.

0.6 For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS : 2-1960*. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

1. SCOPE

1.1 This standard specifies requirements for non-automatic, pressure steam sterilizers, vertical, cylindrical type designed for working pressure of 126 kN/m² (1.26 kgf/cm² approx) gauge but shall be set to operate at 105 kN/m² + 15 kN/m² (1.05 + 0.15 kgf/cm² approx) gauge pressure (corresponding temperature of the saturated steam inside the chamber is minimum 121°C).

2. TERMINOLOGY

2.1 Sterilizer — For the purpose of this standard, the sterilizer shall mean a steam pressure appliance used for the destruction of bacteria and related organisms. In the process of sterilization the probability of occurrence of a viable micro-organism in a medical product is reduced to less than 10⁻⁶.

3. DESIGN

3.1 The sterilizer shall consist of a chamber with a surrounding steam jacket and a lid on the top.

3.2 The sterilizer shall be designed to operate on steam to be generated inside the jacket, by means of electrical power or kerosine stove or gas or combination of these, subject to the purchaser selecting one or the other heating arrangements.

3.3 The sterilizer shall be capable of performing the following operations constituting one full cycle of sterilization:

- a) Generate steam and build up working pressure in the jacket without admitting it to the chamber;
- b) Admit steam to the chamber and allow it to build up to working pressure and temperature (maintaining the pressure in the jacket) and retaining the working pressure for at least 2 hours;
- c) Exhausting the chamber pressure, retaining the jacket pressure; and
- d) Drying of load in chamber (if required) through the circulation of dry, filtered air entering through a drying system.

*Rules for rounding off numerical values (revised).

4. SHAPE AND SIZE

4.1 Shape — Sterilizer shall have a cylindrical shape.

4.2 Size — The size of a sterilizer shall be determined by the size of the inside of the chamber. The standard sizes shall preferably be 30 cm dia $\times$ 50 cm deep or 40 cm dia $\times$ 60 cm deep or 50 cm dia $\times$ 60 cm deep. Other sizes may also be permitted as agreed to between the purchaser and the manufacturer provided the performance tests and other requirements of the standard are fulfilled.

5. MATERIAL

5.1 Various components of the sterilizer shall be fabricated from combination of materials given below:

<i>Part</i>	<i>Material</i>
Chamber and jacket	Stainless steel conforming to designation 04Cr18Ni10 or 07Cr17Ni12MO2 and of 2B finish in accordance with Table 8 of IS : 6911-1972*
Lid-ring and lid	Stainless steel of the above composition or gun metal conforming to IS : 306-1968† or Grade 1 or 2 of IS : 318-1981‡.
Outer cover	Stainless steel sheet conforming to the above designation or mild steel sheet cold rolled conforming to IS : 513-1973§ or aluminium conforming to IS : 737-1974 .
Insulation	Any suitable lagging material such as glass wool.

5.2 When joints are soldered or brazed it shall be done with oxy-acetylene, oxy-propane, air-acetylene or air-propane flame.

5.3 All joints for stainless steel shall be fusion welded.

5.4 Piping — All piping shall be from non-corrosive material like stainless steel, brass, copper, etc (Brass or copper piping shall be seamless).

*Specification for stainless steel plate, sheet and strip.

†Specification for tin bronze ingots and castings (*second revision*).

‡Specification for leaded bronze ingots and castings (*second revision*).

§Specification for cold rolled carbon steel sheet (*second revision*).

||Specification for wrought aluminium and aluminium alloys sheet and strip (*second revision*).

6. CONSTRUCTION

6.1 The sterilizer shall consist of two shells (chamber and jacket) each closed at the bottom separately. The two shells are sealed on top either by a lid-ring or by a separate ring.

6.1.1 General arrangement and nomenclature of various parts shall be as shown in Fig. 1.

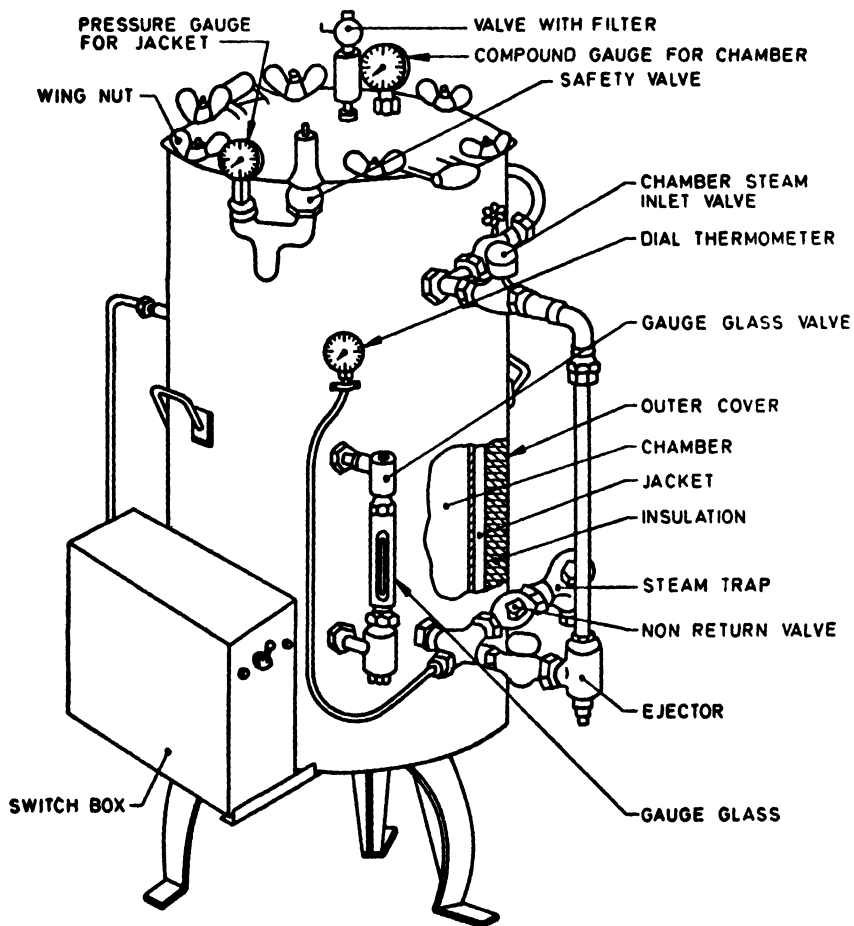


FIG. 1 PRESSURE STEAM STERILIZER, VERTICAL CYLINDRICAL TYPE

6.1.2 Shell — The number of sheets required to form the chamber and jacket shall not exceed two in each case. All the seams shall be fusion welded.

6.1.3 The bottom shall always be formed out of one sheet.

6.2 Lid — The lid shall be provided on the top of the sterilizer. The lid shall be secured to the body when closed.

6.3 Lid Gasket — It shall be one piece without joints moulded of steam resistant, resilient material like neoprene. It shall be capable of effectively sealing the door against internal pressure up to the hydrostatic test pressure. The gasket material shall be durable enough to withstand the working temperature over long periods.

7. FITTINGS

7.1 The fittings as given in the following subclauses shall be provided on the sterilizers :

7.1.1 Individual valves to control the cycle of sterilization, namely,

- a) Admitting steam to the chamber,
- b) Exhausting the chamber steam,
- c) Circulating dry filtered air for drying the chamber, and
- d) Exhausting the jacket steam.

7.1.2 Safety Valve — Where other means of controlling pressure are used, such as pressure switches for electric operation or device for gas flame control, one spring loaded safety valve shall be provided to the jacket.

7.1.3 Where safety valve also acts as relief valve to regulate the operating pressure, an additional spring loaded safety valve, shall be provided, which will prevent an increase in the steam pressure of more than 10 percent of the working pressure.

7.1.4 Temperature control and measurement provision shall be made to incorporate one or more thermocouples in different zones of the chamber of the sterilizer in order to control and measure the temperature of the zone in the chamber.

8. HYDROSTATIC TEST

8.1 On completion of manufacture, the sterilizer chamber shall be subjected to a hydrostatic test of one and a half time, and the sterilizer jacket to twice the working pressure.

8.1.1 The jacket shall be tested at atmospheric pressure in the chamber. The test pressure shall be maintained for not less than 20 minutes, during which time all the accessible parts shall be examined. There shall be no sign of leakage, sweating, weakness or permanent deformation.

9. METHODS OF STEAM SUPPLY TO STERILIZERS

9.1 The steam shall be generated inside the jacket either electrically or by kerosene stove or by gas. In case it is electrically heated the electric load shall preferably be as follows. Safety requirements according to IS : 302-1979* shall be followed.

- a) For sterilizers 30 cm dia × 50 cm deep, 3 kW single phase 230 volts, 50 c/s.
- b) For sterilizers 40 cm dia × 50 cm deep, 6 kW, 440 V, 3-phase, 50 c/s.
- c) For sterilizers 40 cm dia × 60 cm deep, 9 kW, 440 V, 50 c/s, 3 phase.
- d) For sizes other than above the electrical load shall be as agreed to between the purchaser and the supplier.

9.2 Kerosene or Gas Stove Heating — The steam may be generated inside the jacket by externally heating it by kerosene or gas stoves.

9.3 Low Water Protection — Low water protection for heaters shall be provided, to cut-off electric supply to heaters through a contactor if the water level runs below the heater level.

9.3.1 Pressure Control — Working pressure in case of electrically controlled sterilizers shall preferably be controlled through a pressure switch connected to the jacket.

9.4 Switch Box — The contactor, switches and pilot lights shall be located in one box mounted on the stand of the sterilizer.

9.5 Jacket Drain — Suitable connection preferably with valve shall be provided for draining the jacket water.

9.5.1 The sterilizer shall be provided with gauge glass of wall thickness at least 1 mm to indicate water level and self-locking gauge glass valves.

10. ACCESSORIES

10.1 When specified by the purchaser the following accessories may be provided.

10.1.1 Tray or Racks — Trays or racks shall be provided in the chamber of size, shape and material as agreed to between the purchaser and the manufacturer.

*General and safety requirements for household and similar electrical appliances (fifth revision).

10.1.2 Thermograph — Chamber drain line may have an arrangement to fix a thermograph at any time.

11. MARKING

11.1 Each sterilizer shall be legibly and indelibly marked with the following:

- a) Identification of the manufacturer;
- b) Code and serial number;
- c) Working pressure;
- d) Hydrostatic test pressure; and
- e) Wattage, voltage, phase and cycle in the case of electrically operated sterilizer.

11.1.1 The sterilizer may also be marked with the Standard Mark.

11.2 The use of the Standard Mark is governed by the provisions of *Bureau of Indian Standards Act, 1986* and the Rules and Regulations made thereunder. The details of conditions under which the licence for the use of Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.

12. OPERATING MANUAL

12.1 Each sterilizer shall be accompanied by an operating manual which shall contain the following information:

- a) Instructions and plan for installation of the sterilizer,
- b) Operation of the sterilizer, and
- c) Routine maintenance and service.

13. PACKING

13.1 Each sterilizer shall be packed as agreed to between the manufacturer and the supplier.

BUREAU OF INDIAN STANDARDS

Headquarters:

Manak Bhavan, 9 Bahadur Shah Zafar Marg, NEW DELHI 110002

Telephones: 323 0131, 323 3375, 323 9402

Fax : 91 11 3234082, 91 11 3239399, 91 11 3239382

Telegrams : Manaksanstha
(Common to all Offices)

Central Laboratory:

Plot No. 20/9, Site IV, Sahibabad Industrial Area, SAHIBABAD 201010

Telephone
8-77 00 32

Regional Offices:

Central : Manak Bhavan, 9 Bahadur Shah Zafar Marg, NEW DELHI 110002	323 76 17
*Eastern : 1/14 CIT Scheme VII M, V.I.P. Road, Maniktoia, CALCUTTA 700054	337 86 82
Northern : SCO 335-336, Sector 34-A, CHANDIGARH 160022	60 38 43
Southern : C.I.T. Campus, IV Cross Road, CHENNAI 600113	235 23 15
†Western : Nanakalaya, E9 Behind Marol Telephone Exchange, Andheri (East), MUMBAI 400093	832 92 95

Branch Offices:

'Pushpak', Nurmohamed Shalkh Marg, Khanpur, AHMEDABAD 380001	550 13 48
‡Peenya Industrial Area, 1st Stage, Bangalore - Tumkur Road, BANGALORE 560058	839 49 55
Gangotri Complex, 5th Floor, Bhadbhada Road, T. T. Nagar, BHOPAL 462003	55 40 21
Plot No. 62-63, Unit VI, Ganga Nagar, BHUBANESHWAR 751001	40 36 27
Kalaikathir Buildings, 670 Avinashi Road, COIMBATORE 641037	21 01 41
Plot No. 43, Sector 16 A, Mathura Road, FARIDABAD 121001	8-28 88 01
Savitri Complex, 116 G. T. Road, GHAZIABAD 201001	8-71 19 96
53/5 Ward No. 29, R. G. Barua Road, 5th By-lane, GUWAHATI 781003	54 11 37
5-8-58C, L. N. Gupta Marg, Nampally Station Road, HYDERABAD 500001	20 10 83
E-52, Chitaranjan Marg, C-Scheme, JAIPUR 302001	37 29 25
117/418 B, Sarvodaya Nagar, KANPUR 208005	21 68 76
Seth Bhawan, 2nd Floor, Behind Leela Cinema, Nawal Kishore Road, LUCKNOW 226001	23 89 23
Patliputra Industrial Estate, PATNA 800013	26 23 05
T. C. No. 14/1421, University P. O. Palayam, THIRUVANANTHAPURAM 695034	6 21 17
NIT Building, Second Floor, Gokulpat Market, NAGPUR 440010	52 51 71
Institution of Engineers (India) Building, 1332 Shivaji Nagar, PUNE 411005	32 36 35

*Sales Office is at 5 Chowringhee Approach, P. O. Princep Street,
CALCUTTA 700072

27 10 85

†Sales Office is at Novelty Chambers, Grant Road, MUMBAI 400007

309 65 28

‡Sales Office is at 'F' Block, Unity Building, Narashimaraaja Square,
BANGALORE 560002

222 39 71

**AMENDMENT NO. 1 AUGUST 1992
TO
IS 3829 (Part 3) : 1985 SPECIFICATION FOR STEAM
STERILIZERS
PART 3 PRESSURE STERILIZERS, VERTICAL CYLINDRICAL
TYPE**

[*Page 8, clause 9.1 (c)*] — Substitute '50' for '40'.

(MHD 14)

Reprography Unit, BIS, New Delhi, India

AMENDMENT NO. 2 AUGUST 1998
TO
IS 3829 (PART 3) : 1985 SPECIFICATION
FOR STEAM STERILIZERS
PART 3 PRESSURE STERILIZERS, VERTICAL
CYLINDRICAL TYPE

(*Page 5, clause 5.1, informal table, col 2, first para*) — Substitute the following with the existing:

‘Stainless steel conforming to designation X04Cr19Ni9 or X02Cr19Ni10 and of 2B finish in accordance with IS 6911 : 1992’.

[*Page 8, clause 9.1(b)*] — Substitute ‘60 cm deep’ for ‘50 cm deep’.

[*Page 8, clause 9.1(c)*] — Substitute ‘50 cm dia’ for ‘40 cm dia’.

(MHD 14)